

REMARKS

I. Status of the Claims

Claim 11 is withdrawn from consideration as a non-elected invention. Claims 12-21 are pending. Claims 12-14, and 19 have been amended and new claims 22-23 added. The new claims find support in original claim 14. No new matter has been added by these amendments, and no estoppels are intended thereby.

II. Rejection under 35 U.S.C. § 112, second paragraph

The Examiner maintains that Claim 13 is vague, indefinite, and confusing in the recitation of "insulins and their analogs" because it is "unclear what is intended to be encompassed by "analog" in this context. Applicants direct the Examiner to page 3, lines 28 -32, of the specification where non-limiting examples of analogs of insulin are described. Further the Examiner maintains that "corresponding precursors" of these analogs are not set forth. Applicants again direct the Examiner to page 3, lines 22-26, of the specification where corresponding precursors are discussed. The specification further cites preproinsulins as an example of corresponding precursors. See page 4, lines 4-6 of the specification. Based on these disclosures, one of ordinary skill of art thus would not find the terms vague, indefinite, or confusing. Thus, Applicants traverse this rejection and request its withdrawal.

Claim 14 is amended to depend from Claim 12 and thus is no longer "incomplete in depending on a non-elected claim."

Claim 19 has been amended to correct a typographical error and is supported at page 4, lines 8-9.

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The Examiner maintains that Claims 12-21 are incomplete in the absence of a recovery step of the product produced. Applicants have amended claims 12 and 13 to add a step wherein the claimed biomolecules are obtained. Support for this amendment is found at page 2, line 1 and lines 34-35.

The Examiner further maintains that Claims 12 and 13 are vague, indefinite, and confusing in the recitation of "substantially no pores." Applicants respectfully direct the Examiner to page 3, lines 9-21, of the specification in which "substantially no pores" is defined as meaning "no or almost no pores which are large enough that the enzymes can bind to the support within these pores." Thus, the phrase "substantially no pores" is definite as used in the general guidelines of the specification. See *In re Mattison*, 509 F.2d 563 (CCPA 1975); MPEP §2173.05(b).

In light of the foregoing, Applicants respectfully request that the rejections under 35 U.S.C. § 112, second paragraph, be withdrawn.

III. Claim Rejections under 35 U.S.C. § 102(b)

Claim 12 is rejected under 35 U.S.C. § 102(b) as being anticipated by *Lorenzen et. al.* for reasons set forth on page 4 of the Office Action.

A rejection under § 102 is proper only when the claimed subject matter is identically described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); see also M.P.E.P. 706.02(a) ("[f]or anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly").

Claim 12 is drawn to a process for enzymatic extraction of biomolecules. The Examiner maintains *Lorenzen et al* teaches enzymatic extraction of phosphopeptides

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from casein using "a polymeric support material which has no pores or substantially no pores, such as oxirane acrylic beads using trypsin." The *Lorenzen* reference discloses that the oxirane beads are Eupergit C. Applicants teach however, that Eupergit C is not a pore free support or substantially pore free support and the use of this support did not achieve the benefits of the invention. See page 4, lines 15-24 of the specification. By comparison, Eupergit C1Z, a pore free support, was used and did achieve the benefits of the invention. See page 4, lines 25-36 of the specification. Accordingly, this reference does not disclose every aspect of Claim 12 either explicitly or impliedly. For at least this reason, Applicants respectfully request withdrawal of this rejection.

IV. Rejection under 35 U.S.C. § 103(a)

Claims 12-21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Jakubke et al.* taken with *Lorenzen et al.*, *Eckstein*, *Huwig et al.*, and *Hillegas et al.*.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate that there is some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of a reference or combine the teachings of the references. See M.P.E.P. § 2143. In the present case, the above criteria have not been established.

Jakubke, *Lorenzen*, *Eckstein* and *Huwig* do not teach the use of a "polymeric support ...wherein the polymeric support material has no pores or substantially no pores." The Examiner asserts that *Jakubke* teaches the "extraction of insulin using trypsin immobilized in a carrier which appears to be substantially non-porous" and cites to the examples of *Jakubke* for support. The examples set forth in *Jakubke* teach the use of Pericellulose as the carrier. See Examples 1 and 3. However, Pericellulose,

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which is regenerated cellulose, is a porous carrier and thus does not teach the benefits of the invention.

Further, the Examiner asserts that "the use of non-porous carriers in the enzymatic production and extraction of biomolecules is old and well known in the art" as demonstrated by *Lorenzen*. Office Action at 4. However, as discussed above, the *Lorenzen* reference discloses that the oxirane beads are Eupergit C. As discussed above, applicants teach that Eupergit C is not a pore free support and the use of this support did not achieve the benefits of the invention. The Examiner asserts that "*Eckstein* teaches the use of an Eupergit carrier in a similar process of immobilizing trypsin, while *Huwig et al.* discloses the use of Eupergit C250L for an enzymatic bioconversion." *Id.* However, *Eckstein* discloses the use of Eupergit C or VA-Biosynth as the carriers, neither of which provide a pore free or substantially pore free support. *Huwig* discloses the use of Eupergit C250L, which is also not a pore free or substantially pore free support, and thus the use of this support does not achieve any of the benefits of the invention. See page 2, lines 20-27, page 4, lines 15-16 of the specification.

Regarding the *Hillegas* reference, the Examiner asserts that "*Hillegas et al.* tout the advantages of using a non-porous carrier in various applications." Office Action at 4. While *Hillegas* teaches the use of a non-porous bead, it fails to teach a polymeric support comprising one or more enzymes bonded thereto. *Hillegas* teaches a collagen-coated polystyrene microcarrier bead system but says nothing about using microcarrier beads for performing enzymatic chemical reactions. Thus, one of ordinary skill in the art would have no motivation to combine *Hillegas*, which is limited to biological applications

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of polymer beads, with the other references which are directed to enzymatically cleaving biomolecules using carriers which are neither pore free or substantially pore free.

For these reasons, the Examiner is request to reconsider and withdraw this §103(a) rejection.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration of the pending claims and reexamination of the application. The timely allowance of the pending claims is respectfully requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0196.

Respectfully submitted,

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Appendix-Amended Claims

--12. (Amended) A process for enzymatic extraction of biomolecules, comprising:

providing a polymeric support comprising one or more enzyme bonded thereto, wherein the polymeric support material has no pores or substantially no pores; extracting said biomolecules from the group consisting of peptides, proteins, oligosaccharides, and polysaccharides; and

obtaining said biomolecules.

--13. (Amended) A process for extraction, comprising:

providing a polymeric support comprising one or more enzymes bonded thereto, wherein the polymeric support material has no pores or substantially no pores; extracting insulins or their analogs from corresponding precursors; and

obtaining said biomolecules.

--14. (Amended) The process as in [claims 11-13] claim 12, in which said polymeric support material is a copolymer of the monomers methacrylamide and N,N'-bis(methacrylamide). --

--19. (Amended) The process as claimed in 17, wherein said enzyme has activity of [0.5] 0.05 to 0.5 U/ml.--

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